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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/761,535 | 01/21/2004 | David Tyvoll | 200314393-1 | 3304 |

22879 7590 09/28/2007

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| EXAMINER | |
|---|---|
| WALLENHORST, MAUREEN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1743 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 09/28/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/761,535 | TYVOLL ET AL. | |
| | Examiner | Art Unit | |
| | Maureen M. Wallenhorst | 1743 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :1/21/04, 6/28/04, 8/20/04, 4/20/05.

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprises". Correction is required. See MPEP § 608.01(b).

3. Claims 8, 24 and 30 are objected to because of the following informalities: On lines 2-3 of claim 8, the phrase "before delivering the blood sample the test chamber" does not make proper sense. On line 1 of claim 24, the word "deinfes" is misspelled. On the last line of claim 30, the phrase "with the means for identifying a quantity the glucose" does not make proper sense. Appropriate correction is required.

4. Claims 12-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite and incomplete since it is not clear where the electrode arrangement is located in relation to the fluid flow path and the sensor. Is the electrode arrangement disposed in the fluid flow path near the sensor?

On line 2 of claim 23, the phrase "the top wall of the test chamber" lacks antecedent basis.

On the last two lines of claim 28, the phrase "to measure the property of the blood sample to repel cells from the electrode arrangement" is indefinite and does not make proper sense since the specification describes the invention as the spatially varying electric field produced by the electrode arrangement acting to repel cells away from the sensor, not away from the electrode arrangement. It is the electrode arrangement that causes the spatially varying electric field, and the sensor that measures the property of the blood sample in the absence of cells.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-26 and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAleer et al (US 6,241,862) in view of Wang et al (US 6,596,143, submitted in the Information Disclosure Statement filed on January 21, 2004).

McAleer et al teach of a disposable test strip for use in a meter to electrochemically measure glucose in a blood sample. McAleer et al teach that the presence of red blood cells in a blood sample serves to interfere with the glucose measurement since high hematocrit samples result in readings that are lower than the true value, while low hematocrit samples result in readings that are higher because the blood cells tend to foul the surface of an electrode in the test strip and limit electron transfer. The test strip comprises a substrate 10 on which two conductive elements 14 and 16 are located. The conductive elements 14 and 16 are connected by leads to contacts 11, 12 and 13. Together, the conductive elements 14 and 16 act as a sensor for electrochemically measuring glucose in a blood sample. A non-conductive integrated reagent/blood separation layer 17 is applied over the conductive element 16. The integrated reagent/blood separation layer provides a barrier to the passage of interferants such as cells and macromolecules to the conductive sensor element resulting in a test strip with superior properties. The integrated reagent/blood separation layer also contains therein reagents such as enzymes that electrochemically react with glucose. A second non-conductive layer 71 can also be disposed over the integrated reagent/blood separation layer 17. This layer is formed from a composition that is identical to the first integrated reagent/blood separation layer 17 except that the enzyme reagents are omitted. This layer 71 further isolates the conductive sensor element 16 from contact with oxygen-carrying red blood cells. When the test strip is inserted into a meter,

the contacts 11, 12 and 13 make an electrical connection with the meter. A blood sample is applied to a fluid flow path on the test strip where it first comes into contact with the layer 71 and then layer 17. The integrated reagent/blood separation layer 17 comprises reagents for the electrochemical detection of glucose dispersed in a non-conductive matrix effective to exclude red blood cells from the surface of the sensor conductive element 16 while permitting access to the first conductive element 16 by the soluble electroactive glucose. The blood sample containing a reduced concentration of red blood cells (i.e. an enriched plasma portion) then travels to a test chamber in the test strip containing the conductive elements 16, 17 for measurement of the glucose in the sample. The test meter applies a voltage to the conductive elements 16, 17, and the current level produced as a result of the glucose coming into contact with the conductive sensor elements is measured. See Figures 1A, 1B and 7, lines 22-67 in column 2, lines 1-30 in column 3, lines 1-42 in column 4, lines 1-9 in column 8 and lines 7-17 in column 9 of McAleer et al. McAleer et al fail to teach that the red blood cells in the blood sample measured with the glucose test strip can be removed by applying a dielectrophoretic spatially varying electric field to the blood sample.

Wang et al teach of a device and method for manipulating, transporting and concentrating particles such as cells using traveling-wave dielectrophoresis. The device comprises a bio-chip having three electrically independent branches. Each of the branches forms a channel with a top wall, a bottom wall and side walls. Each of the channel branches also comprises a plurality of electrodes therein capable of producing a spatially varying electric field when the electrodes are connected to out-of-phase signals. The branches meet at a common junction. The electrodes in each of the branches can generate spatially varying dielectrophoretic fields that serve to move

particles in each of the branches towards the common junction so as to concentrate the particles at the junction. In the embodiment depicted in Figure 2, the device comprises an electrode set 110a, 110b and 110c in each of three channels. The electrodes 114 in each channel receive electrical signals, which are out-of-phase with each other, so that a traveling wave electric field is induced in each branch, which acts on and moves particles therein. The three sets 110a, 110b and 110c of electrodes 114 are capable of producing traveling wave electric fields along respective branches, in which the three sets of electrodes are electrically independent of each other and meet at a common junction 150. Forces generated by the three sets 110a, 110b and 110c act on particles at the common junction 150 to switch particles from one branch into another. In one embodiment, Wang et al teach of manipulating cells found in blood. A blood sample is introduced into the device, and the red blood cells therein are initially distributed randomly over the electrode sets of the branches. Four-phase electrical signals are applied to the electrodes of each branch. Red blood cells are transported by the traveling wave dielectrophoresis forces in the direction opposite of that of the traveling direction of the traveling electric field. Using the phase sequences shown in Figure 10A, all of the red blood cells on the three branches are concentrated into the central junction region between the three branches. Using other phase sequences, the red blood cells can be selectively transported among the three different branches. See Figures 1A, 1B and 2, lines 29-47 in column 2, lines 46-64 in column 5, lines 14-49 in column 6, lines 44-67 in column 18, lines 61-67 in column 37 and lines 1-30 in column 38 of Wang et al.

Based upon the combination of McAleer et al and Wang et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to remove the red

blood cells from the blood sample tested for glucose using the glucose test strip taught by McAleer et al by using the spatially varying electric fields taught by Wang et al since McAleer et al teach that it is important to remove red blood cells from blood samples being electrochemically measured for glucose in a test strip in order to obtain accurate results, and Wang et al teach that red blood cells can be concentrated and removed from the plasma portion of blood by being subjected to traveling wave, spatially varying electric fields, which is equivalent to filtering out the red blood cells with the blood separation layer taught by McAleer et al since both processes achieve the separation of red blood cells from the plasma portion of blood. With regards to claims 21-24, it would have been obvious to one of ordinary skill in the art to vary the configuration of the electrodes used to produce a spatially varying electric field and the conductive sensor electrode in the glucose test strip taught by McAleer et al to the configurations recited in these claims since such positioning is a result effective parameter that can be experimentally changed for the optimization of a particular measurement. With regards to claim 32, it would have been obvious to one of ordinary skill in the art to apply the spatially varying electric field taught by Wang et al to the blood sample in the glucose test strip taught by McAleer et al multiple times in different locations of the test strip in order to further concentrate and move the red blood cells away from the sensor electrode and to further purify the plasma so as to obtain an enhanced, more accurate measurement of glucose concentration.

9. Claim 27 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests a hybrid electrode element having both an electrode configuration for producing a

spatially varying electric field and a sensor electrode portion for detecting glucose concentration in a blood sample on the same element.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Phillips et al who teach of an optical glucose test strip and meter, and Black et al who teach of an electrochemical glucose test strip having a membrane to separate out red blood cells.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

September 18, 2007

Maureen M. Wallenhorst
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GROUP [redacted] 1700